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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,484	11/28/2001	Yen Choo	8325-2004 G8-US1	2713

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ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,484

Applicant(s)

CHOO ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10,11,13-18,21-26,31,34,35 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,7,8,10,11,13-18,21-26,31,35 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 7 September 2004 in response to the Non-Final Office Action mailed 3 June 2004. Claims 1-18, 21-33, 35 and 38-47 were withdrawn from consideration and claim 34 was considered in the 3 June Office Action. Claims 6, 9, 12, 27-30, 32 and 33 were canceled and claims 1-5, 8, 13-15, 18, 21, 22, 34, 38-40, 46 and 47 were amended in the 7 September Paper. Claims 1-5, 7, 8, 10, 11, 13-18, 21-26, 31, 34, 35 and 38-47 are pending and claim 34 is under consideration.

Election/Restrictions

Under the heading "Restriction", Applicant states, "Applicants expressly reverse their right to rejoinder of pending process claims" (emphasis added) and "Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application." Although it is suspected that "reverse" is a typographical error and Applicant's intention is to "reserve" their right to rejoinder of process claims, it is noted that, should the product claim be found allowable, the withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. In the event of rejoinder, the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply. See MPEP § 804.01.

Response to Amendment and Arguments

Art Unit: 1636

Applicant is reminded that the revised Rule 1.121 requires that withdrawn claims be indicated as such in the status identifier. In the present amendment, withdrawn claims that have been amended are identified only as “currently amended”. The proper status identification for a withdrawn claim that is also presently amended is: “withdrawn” or “withdrawn and currently amended”.

Claim Rejections - 35 USC § 102

Rejection of claim 34 under 35 U.S.C. 102(a) as being anticipated by Uchida *et al.*, under 35 U.S.C. 102(b) as being anticipated by any one of Nicola, Carpenter *et al.* or Alberts *et al.* and under 35 U.S.C. 102(e) as being anticipated by Menzel *et al.* US Patent No. 6,265,174 is withdrawn in view of the amendment to the claim.

Claim 34 stands rejected under 35 U.S.C. 102(b) as being anticipated by McEwan *et al.* (1996) *BioEssays* 19 :153-160 for reasons of record. In response to the *prima facie* rejection of record, Applicant has amended the claim such that at least one of the first or second polypeptides of the switching system is limited to binding to DNA. In the paragraph bridging pages 153-154, McEwan *et al.* describes in detail the DNA binding domain comprised within the glucocorticoid, estrogen and retinoid receptor proteins comprised within the switching systems disclosed in Table 1. Thus, the switching systems of McEwan *et al.* comprise each of the elements of the switching system of the instant claim 34, and the claim stands properly rejected under 35 USC §102(b).

Art Unit: 1636

New Grounds

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by any one of Crabtree *et al.* US Patent No. 6,046,047; Natesan *et al.* US Patent No. 6,479,653; or Natesan US Patent No. 6,015,709, each of which were made of record in the IDS filed 7 September 2004.

Crabtree *et al.* discloses a switching system comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, wherein the first protein comprises a GAL4 DNA binding domain (see especially Examples 7 and 8, beginning in column 41). The switching system described by Crabtree *et al.* is the same as the switching system of the instant claim 34.

Each of Natesan *et al.* (especially Figure 1 and the caption thereto) and Natesan (see Figure 3 and the caption thereto) disclose a switching system comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, wherein the first protein comprises a DNA binding domain. The switching systems described by Natesan *et al.* and Natesan are the same as the switching system of the instant claim 34.

Art Unit: 1636

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Pomerantz *et al.* 6,326,166 (made of record in the IDS filed 7 September 2004).

Pomerantz *et al.* (especially Figure 5 and the caption thereto) discloses a switching system comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, wherein the first protein comprises a DNA binding domain. The switching system described by Pomerantz *et al.* is the same as the switching system of the instant claim 34.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7 September 2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1636


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yueel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER